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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/720,762      | 12/28/2000  | Kazuyuki Yanase      | K0208.014           | 5214             |

23723 7590 08/06/2003

Patterson Belknap Webb & Tyler, LLP  
Attention: I.P. Docketing  
1133 Avenue of the Americas  
New York, NY 10036

EXAMINER

SAYOC, EMMANUEL

ART UNIT

PAPER NUMBER

3746

DATE MAILED: 08/06/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Intervenor  
VTS 104  
ZPM

|                              |                            |                  |
|------------------------------|----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.            | Applicant(s)     |
|                              | 09/720,762                 | YANASE ET AL.    |
|                              | Examiner<br>Emmanuel Sayoc | Art Unit<br>3746 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 30 June 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-3 and 6-10 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-3 and 6-10 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 28 December 2000 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. This office action is in response to the amendments of 6/30/2003. In making the below rejections and/or objections the examiner has considered and addressed each of the applicants arguments.

#### *Specification*

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

#### *Claim Objections*

3. Claim 1-3, and 6-10 are objected to because of the following informalities: claim 1 recites a barrel, which is not clearly defined as the cylinder of the syringe comprising a tubular body with an inner and outer surface. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136), and in further view of Ito (U.S. 5,063,025).

With respect to claims 1, and 6-8, Trull et al., in Figure 6, disclose a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner

surface of the syringe barrel (60). A restriction (labeled by the examiner on Figure 6 attached to the end of this office action) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid if formed into a tapered slant (also labeled by the examiner on Figure 6).

The Trull et al. differs from the claimed invention in that there is no disclosure of one or both of the peripheral side surface that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin. Ito, in column 5 lines 1-7, discloses that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (TEFLON). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene or polypropylene, in order to achieve optimum gasket lubrication, functionality, and protection within a syringe device.

With respect to claim 3, the Trull et al. apparatus comprises a tapered slant with a first and second plunger diameter. The examiner has labeled these embodiments on the marked up Figure 6.

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about 5mm. Furthermore, with respect to claims 6-8, there is no disclosure of the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claim 3 and 6-8, where the general

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conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

6. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Ito, as applied to claim 1, and in further view of Akaike et al. (U.S. 5,061,247).

Trull et al., as modified by Ito, set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the hardness of the gasket being between 55 to 60 (JIS hardness meter). Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device.

With respect to claims 9 and 10, a second tapered slant is formed between the peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel and the restriction. The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus does not impose any structural limitations

upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

***Response to Amendment***

7. The objection to the drawings is hereby withdrawn.
8. The objections to claims 4 and 5 are hereby withdrawn.
9. The rejection for claim 6, under 35 U.S.C. 112 second paragraph, is hereby withdrawn.

***Response to Arguments***

10. Applicant's arguments filed 6/30/2003 have been fully considered but they are not persuasive. The applicant claims that the combination of Trull et al. and Ito is improper on the grounds that the Ito device is directed to a syringe for liquid chromatography, and that the Ito device addresses fluid pumping difficulties other than that of injecting liquid into the human body such as leakage due to heat and pressure of sterilization. The combination is directed to applying polyethylene fluoride, TEFLON, lamination on the plunger, as taught by Ito, onto the Trull et al. device. This is intended to allow a virtually frictionless sliding motion of the plunger and also to provide a protective seal on the plunger. No lubrication on the plunger is critical in preventing contaminating fluids injected into the body. Also the protective seal allows for the plunger to be easily sterilized. Furthermore the Ito device, directed at supercritical fluid pumping applications, which involves extreme temperature and pressure conditions would have been well suited for medical purposes.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited to further show the state of the art with respect to gaskets for syringes.

U.S. Pat. 5, 688, 252 to Matsuda et al.

U.S. Pat. 5, 397, 313 to Gross

U.S. Pat. 4, 303, 070 to Ichikawa et al.

The applicant is invited to note the tapered slants in the listed references.

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***Contact Information***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emmanuel Sayoc whose telephone number is (703) 305-0054. The examiner can normally be reached on M-F 8 A.M. - 6 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Thorpe can be reached on (703) 308-0102. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.



Emmanuel Sayoc  
Patent Examiner  
Art Unit 3746



Cheryl J. Tyler  
CHERYL J. TYLER  
PRIMARY EXAMINER

ECS  
August 5, 2003